CARD GUARD
Scientific Survival LTD.

JAN 13 2005

PMP4 SelfCheck™ ECG
510(k) Summary of Safety and Effectiveness

K042254

Submitter: Card Guard Scientific Survival Ltd.,

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Date Prepared: December 19, 2004

1. Definition

PMP4 SelfCheck™ ECG allows transmitting multiple ECG recordings of 1 or 12-lead to a device (PMP^4 or compatible generic PDA or mobile telephone with Bluetooth support) allowing physician to monitor the device output remotely.

Multi-functional Patient Monitor:

- Built-in 1-lead ECG monitor
- 12-lead ECG monitor using an external patient cable

2. Intended Use

The PMP4 SelfCheck™ and Card Guard Heart Screening Service are intended for self-testing by patients and by health care professionals at home and at medical settings. This 12- lead and 1-lead electrocardiogram (ECG), allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the PMP4 SelfCheck™ ECG is intended for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding heart (Palpitations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Contraindications for Use:

In order to use this service, the patient must be able to perform all of the following:

- Read and understand the User's Manual
- Place the PMP4 SelfCheck™ ECG on his/her chest and hold it steadily for at least 30 seconds.
- Hear the "beeps" for low battery.
- Speak and understand English.
- Operate a PDA or cell phone (hand-held devices).
- Operate a simple, push-button device.

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons who have been diagnosed with the following conditions should consult their physician before using this service:

- Blockage of the arteries of the heart
- Heart valve problems
- Heart transplant
- Congestive heart failure
- Loss of consciousness

If the patient has any of these conditions, CG will need to obtain authorization from their physician within 35 days of enrollment in the service.

Warning:

This non- standard 12- lead and 1- lead electrocardiogram (ECG), which is measured using the SelfCheck™ ECG, should not be used for diagnostics in comparison to the standard 12 lead ECG obtained with standard electrode placement.
Use of SelfCheck™ ECG with 12-lead cable is by physician prescription only.
This device should not be used with pacemakers or implanted defibrillators and cannot predict or diagnose a heart attack or be used for chest pain monitoring.
The SelfCheck™ ECG is not a defibrillation –proof device.

Need for Signed Physician Agreement (12- lead ECG):

Your agreement indicates you understand that CG (or affiliate) will contact your physician to verify in writing that you are their patient and that they are willing to be contacted in cases where there are clinically significant events involving your care.

Your agreement indicates you understand that if written verification is not received from your physician within 35 days of your enrollment, you will not be able to utilize any aspects of the CG (or affiliate) service until such verification is received by CG (or affiliate).

Your agreement certifies you understand that this service is not a substitute for physician care and that this is only a screening service.

- Low Battery detection and audio warning

5. User Interface

The PMP4 SelfCheck™ ECG user interface incorporates the following controls and signals:

- On/off control button
- SEND control button (optional)
- Fluctuating transmission sound
- Low battery warning

6. Substantial Equivalence

The substantially equivalence to the following predicate devices is claimed:

CG-2211	1 Lead ECG Transmitter (QTC)	K012223	Decision Date 07/28/01
CG-7100	12 Lead Personal ECG Transmitter	K964836	Decision Date 07/28/97

PMP4 SelfCheck™ ECG is schematically identical to CG-2211 ECG Transmitter K012223, except it includes a 12 Lead option and uses the Bluetooth technology instead of transtelephonic transmission. It is also proposed as a non-prescription device (OTC).

The Intended use is similar: self-testing by patients. Both devices transmit a limited period of heart activity.

The common feature with CG-7100 (K964836) ECG Transmitter is the 12- Lead option. Both, the PMP4 SelfCheck ECG and the CG-7100 should not be used for diagnostics in comparison to the standard 12 lead ECG obtained with standard electrode placement and do not provide quality ECG data. By comparing the safety tests and performance tests of the SelfCheck™ ECG to those of the CG-7100, it can be concluded that its safety and efficacy are not derogated.

7. Design Controls and Hazard Analysis

The Card Guard's product design procedure, and QA and QC policy, formalize the design and production process and assure that all respective requirements are met. In the framework of the Design Controls laboratory testing were conducted to verify and validate the PMP4 SelfCheck™ ECG compliance with all design specifications.

The device biocompatibility was evaluated and found to be satisfactory.

The device Level of Concern criteria were evaluated and PMP4 SelfCheck™ ECG was characterized as a moderate level of concern system.

The system safety and risk analysis conducted for PMP4 SelfCheck™ ECG provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly affect the patient.

8. Conclusions

PMP4 SelfCheck™ ECG constitutes a safe and reliable means for transmitting ECG data. Its material composition and operation present no adverse health effect or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Boris Aradovsky
VP, QA and Regulatory Affairs
Card Guard Scientific Survival Ltd.
2 Pekeris St. P.O.B. 527
Rehovot 76100
ISRAEL

Re: K042254
Trade Name: PMP4 SelfCheck™ ECG
Regulation Number: 21 CFR 870.2920
Regulation Name: Transmitters and Receivers, Electrocardiograph, Telephone
Regulatory Class: II (two)
Product Code: DXH
Dated: December 29, 2004
Received: January 03, 2005

Dear Ms. Aradovsky:

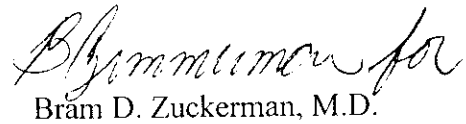
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K042254/S2

Device name: PMP4 SelfCheck™ ECG

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Prescription Use __√____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
sion of Cardiovascular Devices
0(k) Number K042254